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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,728	09/20/2000	Lawrence W. Stanton	SCIOS.013A	8743

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KNOBBE MARTENS OLSON & BEAR LLP
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH, CA 92660

EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/665,728	Applicant(s) STANTON ET AL.	
	Examiner Eileen B. O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, in so far as they are drawn to nucleic acids encoding a polypeptide have the sequence of SEQ ID NO: 1 or the complements thereof, vectors, host cells and method of recombinantly producing polypeptide, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1,for example.

II. Claim 1, in so far as it is drawn to antisense oligonucleotides capable of hybridizing with and inhibiting translation of mRNA encoded by a gene encoding a polypeptide of SEQ ID NO: 1, classified in class 536, subclass 24.5.

III. Claims 9-12, drawn to a polypeptide of SEQ ID NO: 1, classified in class 530, subclass 350.

IV. Claims 13, 15 and 16, drawn to antibodies to a polypeptide of SEQ ID NO: 1, classified in class 350, subclass 388.22, for example.

V. Claims 14, 17 and 18, in so far as they are drawn to an antagonist of unspecified composition to the polypeptide of SEQ ID NO:1, class and subclass undeterminable.

VI. Claims 14, 17 and 18, in so far as they are drawn to an agonist of unspecified composition to the polypeptide of SEQ ID NO:1, class and subclass undeterminable.

VII. Claim 19, in so far as it is drawn to a method of treatment comprising administration of a polypeptide of SEQ ID NO: 1, class 514, subclass 2.

VIII. Claim 19, in so far as it is drawn to a method of treatment comprising administration of an antagonist of unspecified composition to the polypeptide of SEQ ID NO: 1, class 514, subclass 2, for example.

IX. Claim 19, in so far as it is drawn to a method of treatment comprising administration of an agonist of unspecified composition to the polypeptide of SEQ ID NO: 1, class 514, subclass 2, for example.

X. Claim 20, drawn to a method of treatment comprising administration of an antibody to the polypeptide of SEQ ID NO: 1, class 514, subclass 2.

XI. Claims 21 and 22, drawn to a method for screening a subject for disease by comparing expression of the polypeptide of SEQ ID NO: 1 in the subject and a normal subject, classified in class 436, subclass 501, for example.

XII. Claims 23-29, drawn to olgionucleotide arrays and method for detecting disease using them, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related in that some of the antisense oligonucleotides of Invention II are related to the nucleic acids of Invention I by virtue of being subsequences of longer disclosed sequences, however, these inventions are patentably distinct both because the nucleic acids of invention II are not required for Invention I, and because they are used in materially different processes which processes are completely different and distinct. The arts of antisense therapy and recombinant

production of proteins are separate and distinct, and require non-coextensive searches.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of invention III can be recovered from natural sources.

Invention III is related to the antibodies of invention IV by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify a compound which binds to it.

Inventions I and inventions IV, VII, X and XI are related in that the polynucleotides of invention I encode the polypeptide, which is used in the method of treatment of invention VII, and which is the cognate antigen necessary for the production of the antibody of invention IV which is used in the method of treatment with the antibody of invention X and which is also used in the method of screening for disease by detecting differential expression of the polypeptide that is invention XI.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in a method of treatment, but the polypeptide can also be used in a method of producing antibodies, which is a materially different method.

Invention III and each of inventions V and VI are related in that the antagonist and agonist of inventions V and VI either inhibit or activate the polypeptide of invention III, but they are all structurally and functionally different chemical compounds, each of which can be made and used without any one or more of the other compounds.

Invention IV and each of inventions V and VI are related in that the antagonist and agonist of the polypeptide may be antibodies, but these antibodies would be structurally and functionally different chemical compounds that would have different effects on the polypeptide.

Similarly, invention IV may be related to inventions VIII and IX as product and process of use. In the instant case, the antibodies may be an antagonist or agonist to the polypeptide and be used in a method of treatment, but the antibodies and therefore methods of treatment would be distinct because they would comprise administration of structurally and functionally different types of antibodies.

Inventions IV and each of inventions X and XI are related as product and process of use. In the instant case the antibodies of invention IV are used in a method of treatment or to detect polypeptide expression, but the antibodies may also be used to purify polypeptide, which is a materially different method.

Invention V and invention VIII are related as product and process of use. The antagonist may be used in a method of treatment, but the antagonist could be used in another method, such as to produce antibodies to it, which is a materially different method.

Invention VI and invention IX are related as product and process of use. The agonist may be used in a method of treatment, but the agonist could be used in another method, such as to produce antibodies to it, which is a materially different method.

Inventions I and each of inventions V, VI, VIII, IX, X, and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of invention I are either a structurally and functionally different chemical compound from those of inventions V and VI, and is not used or defined in the methods of inventions VIII, IX, X and XII.

Inventions II and each of inventions III-XII are also unrelated. In the instant case the antisense nucleotide is a either a structurally and functionally different chemical compound from those of inventions III-VI, and is not used or defined in the methods of inventions VII-XII.

Invention III and each of inventions VIII-XII are also unrelated. In the instant case the polypeptides are not used in the methods.

Invention IV and each of inventions VII and XII are unrelated. In the instant case the antibodies are not used in the methods of treatment with the polypeptide or in the method of screening for disease by detecting DNA expression.

Invention V is unrelated to each of inventions VII and IX-XII. In the instant case the antagonist is not used or defined in the methods.

Invention VI is unrelated to each of inventions VII, VIII and X-XII. In the instant case the agonist is not used or defined in the methods.

The methods of inventions VII-XII are all unrelated to each other. The methods of the different inventions require different starting materials and have different steps and goals.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the need for non-coextensive literature search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara whose telephone number is (703) 308-3312. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler can be reached on (703) 308-6564. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.
November 20, 2001

LORRAINE SPECTOR
PRIMARY EXAMINER